SUMMARY OF INTERVIEW

Applicants thank Examiner Nasser for the helpful and courteous telephonic interview conducted on July 11, 2005 with Applicants' representatives, Laura Johnson and Jim Brauker.

Exhibits and/or Demonstrations

None

Identification of Claims Discussed

All

Identification of Prior Art Discussed

U.S. 6,360,888 to McIvor et al.

Proposed Amendments

Applicants proposed amending Claims 1 and 2 to recite, *inter alia*, a "wholly implantable" analyte measuring device wherein "the multi-region membrane comprises a cell disruptive domain that supports tissue ingrowth."

Principal Arguments and Other Matters

Applicants argued that it was not obvious to modify U.S. 6,010,067 to Shults to use the electrode structure of McIvor, since Applicants have a different motivation to use a larger counter electrode than McIvor. The Examiner noted that further consideration was required and agreed to discuss the case further with applicant after a draft amendment was prepared

Results of Interview

N/A.

REMARKS

Claims 1-10, 12-15, 21-28, and 30-33 are pending in this application. Claims 1-10, 12-15, 21-28, 30, and 32 have been amended. Claims 11, 16-20, and 29 have been canceled. Support for the amendments is found in the specification and claims as filed.

Claim Rejection - 35 U.S.C. § 102(b) - Ito

Claims 1, 2, 21, 24, and 29 have been rejected under 35 U.S.C. §102(b) as anticipated by U.S. 5,384,028 ("Ito"). "A rejection for anticipation under section 102 requires that each and every limitation of the claimed invention be disclosed in a single prior art reference." *See, e.g., In re Paulsen*, 31 U.S.P.Q.2d 1671 (Fed. Cir. 1994). Ito does not disclose every element of Applicants' claims, and therefore cannot be considered an anticipating reference under 35 U.S.C. § 102(b).

Applicants' pending independent Claims 1 and 2 recite a wholly implantable analyte measuring device comprising, *inter alia*, a multiregion membrane "wherein the multi-region membrane comprises a cell disruptive domain that supports tissue ingrowth." Ito is directed to a biosensor having a glucose oxidase immobilized membrane and an albumin immobilized membrane. Ito includes no disclosure or suggestion of a device comprising a multiregion membrane "wherein the multi-region membrane comprises a cell disruptive domain that supports tissue ingrowth" and therefore cannot anticipate Claim 1 or its dependent Claims 2-10, 12-15, and 21-28. Applicants therefore respectfully request withdrawal of the rejection.

Claim Rejection - 35 U.S.C. § 103(a) –Heller et al. in view of Shults et al. and Nagata et al.

Claims 1, 2, 5-10, 12-15, and 22-33 have been rejected under 35 U.S.C. §103(a) as obvious over U.S. 6,392,161 ("Heller et al.") in view of U.S. 6,001,067 ("Shults et al.") and U.S. 4,871,440 ("Nagata et al."). Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). There is no such suggestion or teaching, and, in fact, the disclosures teach away from the invention as recited in the pending independent claims. A *prima facie* case of obviousness cannot be established if the

disclosure of the cited prior art, when taken as a whole, teaches away from the claimed invention. *See, e.g.,* M.P.E.P. § 2141.02.

The Office Action asserts that it would have been obvious to modify Heller et al. to use the electrode structure of Shults et al., as it is merely the substitution of one known equivalent structure for another. Applicants respectfully disagree. Heller et al. disclose a "*small* (e.g., 0.29 mm), recessed, non-corroding metal (e.g., gold, platinum, palladium) or carbon wire electrode for subcutaneous in vivo glucose monitoring" (col. 2, lines 58-60) (*emphasis added*). Heller et al. are concerned particularly with the size of the device and prefer its size to be that as stated at col. 4, line 23: "the outside diameter a of the wire is preferably about 0.25 mm or less, and *the outside diameter b of the insulated wire is preferably about 0.3 mm or less*" (*emphasis added*). Additionally, Example 2 at column 13 discloses the insertion of the sensor "using a *22 gauge Per-Q-Cath Introducer (Gesco International, San Antonio, Tex.) on the rat's thorax, or subcutaneously in the intrascepular area through a small surgical incision*" (see also claims 25 and 31, *emphasis added*). Thus, the glucose sensor of Heller et al. is specifically configured for transcutaneous implantation via an introducer such as a needle (*i.e.*, 22 gauge) and the body of the device (*e.g.*, the portion housing the electronics, etc.) is located outside of the body.

In contrast, Shults et al. is directed to a wholly implantable glucose sensor wherein the electrode and membrane structure are integrally formed on the body that is adapted to be wholly implanted into a host for long term glucose sensing. Specifically, in contrast to Heller et al., considerations of electrode size and method of insertion of the electrodes are not a concern in sensor configuration. The sensor of Shults et al., which includes "a non-conductive body, a working electrode, a reference electrode, and a counter electrode, wherein the electrodes pass through the non-conductive body forming an electrochemically reactive surface at one location on the body and an electronic connection at another location on the body" cannot be merely substituted into the glucose sensor of Heller et al., because the electrode structure of Shults et al. would not yield a glucose sensor that could be implanted using a 22 gauge introducer due to its size, and the structure of Shults et al. would not produce a transcutaneous glucose sensor wherein the sensor electrodes are implanted and the housing and electronics are outside the body. Therefore, the substitution of the structure of the Shults et al. glucose sensor into the Heller et al. glucose sensor would produce a sensor unsuitable for its intended use, namely a transcutaneous

sensor wherein the sensor electrodes are inserted into a host via an introducer needle and wherein the electronics remain outside the body (also known as a "needle sensor" in the art). Accordingly, there is no motivation to combine.

The teachings of Nagata et al. do not overcome the deficiencies of Heller et al. and Shults et al., and in fact, the disclosure teaches away from such a combination. Specifically, the glucose sensing method used by Heller et al. is not concerned with improving oxygen availability. In fact, oxygen needs to be limited in the membrane system of the Heller et al. device in order to achieve acceptable function. The larger counter electrode of Nagata et al. increases the oxygen available to the electrodes. Accordingly, combining the electrode system of Nagata et al. with the device of Heller et al. would result in poorer performance of the "wired enzyme" technology sensor of Heller et al. rather than improved performance. Thus there is no motivation to combine.

It is also noted that Heller et al. is directed to a glucose sensor for short term use (see col. 14, lines 12-24, describing the sensor's failure at 400-600 minutes because of poor electrolytic contact with the skin and its failure after 36 hours by deactivation of the lactate oxidase). Because the sensor is only suitable for short term use, there is no motivation to combine the teachings of Shults et al. related to an angiogenic layer in a long term glucose sensor to obtain Applicants' sensor, which discloses a long term glucose sensor with a "multi-region membrane compris[ing] a cell disruptive domain that supports tissue ingrowth." Moreover, Nagata et al. includes no teaching or suggestion as to a "multi-region membrane compris[ing] a cell disruptive domain that supports tissue ingrowth."

Accordingly, there is no teaching or motivation to combine or modify the teachings of the cited references in such a way as to yield the sensor as presently claimed. A *prima facie* case of obviousness therefore cannot be made, and Applicants respectfully request withdrawal of the rejection.

Claim Rejection - 35 U.S.C. § 103(a) – Heller et al. in view of Shults et al., Nagata et al., and Schulman et al.

Claims 3 and 4 have been rejected under 35 U.S.C. §103(a) as obvious over Heller et al. in view of Shults et al. and Nagata et al., in further view of U.S. 6,119,028 ("Schulman et al."). As discussed above, pending independent Claims 1 and 2, from which Claims 3 and 4,

respectively, depend, are not obvious over Heller et al. in view of Shults et al. and Nagata et al. Schulman et al., which teaches a silicone membrane, does not overcome the deficiencies of Heller et al., Shults et al., and Nagata et al., in that it includes no teaching or suggestion as to a "multi-region membrane compris[ing] a cell disruptive domain that supports tissue ingrowth." Accordingly, Applicants respectfully request withdrawal of the rejection.

Claim Rejection - 35 U.S.C. § 103(a) –Heller et al. in view of Shults et al., Nagata et al., and Ward et al.

Claim 21 has been rejected under 35 U.S.C. §103(a) as obvious over Heller et al., Shults et al., and Nagata et al., in further view of U.S. 6,119,028 ("Ward et al."). As discussed above, pending independent Claim 2, from which Claim 21 depends, is not obvious over Heller et al. in view of Shults et al. and Nagata et al. Ward et al., which teaches a ceramic housing, does not overcome the deficiencies of Heller et al., Shults et al., and Nagata et al., in that it includes no teaching or suggestion as to a "multi-region membrane compris[ing] a cell disruptive domain that supports tissue ingrowth." Accordingly, Applicants respectfully request withdrawal of the rejection.

Conclusion

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns that might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number below.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 8/30/05

By: _____

Rose M. Thiessen
Registration No. 40,202
Attorney of Record
Customer No. 20,995
(619) 235-8550

1888250
082405